

REMARKS

Formal Matters

In the specification, the paragraphs at page 24, lines 9-14 has been amended to correct a minor typographical error.

Claims 29-30, 36-40, 46-49, 52-54 remain in this application. Claims 29, 39 and 49 are amended, and Claims 31-35, 41-45 and 50-51 are cancelled. No new matter is added by the amendments.

Support for the amendments is found throughout the specification, and specifically at least as indicated below:

Claims 29 and 39, patched-2 binding to hedgehog, page 9, lines 22-23.

Claims 29 and 39, 95% sequence identity, page 2, lines 32-33.

Claims 29, 39 and 49, monoclonal antibody, page 8, lines 21-33.

In view of the Examiner's earlier restriction requirement, applicant retains the right to present withdrawn and cancelled subject matter in subsequent prosecution.

Rejection Under 35 U.S.C. § 112, First Paragraph.

Claims 29-50 and 52-54 are rejected under 35 U.S.C. § 112, First Paragraph, allegedly because for failing to comply with the written description requirement because the claims contain new matter.

Specifically, the Examiner asserts that the recited passage at page 49, lines 7-8 only recited monoclonal antibodies that can specifically bind vertebrate *patched-2*, but not antibodies that specifically bind *patched-2*. The Examiner has also asserted that the language of Claims 29 and 39 referring to "[v]ariants having 1 to 5 conservatively substituted, added or deleted amino acid residues" also lacks written support.

Responsive to the first rejection, Applicants respectfully disagree that the specification does not support the subgenus of antibodies that specifically bind to SEQ ID NO:2. For

example, page 24, lines 9-14 discuss monoclonal antibodies that can specifically bind to *patched-2*. The definition of *patched-2* at page 5, lines 5-26, expressly includes SEQ ID NO:2.

Monoclonal antibodies that bind to *patched-2* are described at page 24, lines 9-10. The following text at page 24, lines 10-14 discuss various suitable techniques for measuring the binding specificity, including immunoprecipitation, radioimmunoassay or enzyme-linked immunoabsorbent [sic] (ELISA). The definition of "immunoprecipitation" is the process of precipitating an antigen using an antibody that is specific for that protein. It is often used to identify particular proteins in complexes present in cell extracts. Radioimmunoassay is a process of determining the approximate level of antigen in a solution using a labeled antigen bound to an antibody specific to the antigen. The amount of antigen in the solution is determined by the relative displacement of the labeled antigen. ELISA is a technique involving 2 antibodies, one which is specific to the antigen, and another which is coupled to an enzyme that can elicit a chromogenic or fluorescent signal.

Applicants respectfully submit that one of ordinary skill would know that antibody "binding specificity" means an antibody that binds to one antigen and only to that antigen. However, in light of the examples techniques recited for determining such specificity, it is unambiguously clear, that applicants intended definition of specificity is consistent with that used in the enumerated techniques, which is an antibody that binds only to a single antigen. As a result, Applicants respectfully submit that one of ordinary skill in the art would immediately recognize that the binding specificity contemplated by the claims means an antibody that binds only to SEQ ID NO:2 and not to any other protein.

Responsive to the second rejection, Applicants respectfully disagree that that the specification does not teach conservative substitutions of one to five amino acids of SEQ ID NO:2. However, Applicants' amendment renders the rejection moot.

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 29-50 and 52-54 are rejected under 35 U.S.C. § 112, First Paragraph.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 29-54 are rejected under 35 U.S.C. § 112, Second Paragraph because, allegedly, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

This rejection appears in three parts. In the first part, the Examiner asserts that claims 29 and 39 are indefinite because it is allegedly unclear if the phrase “and (2) which binds to hedgehog” refers to the purified antibody or to the patched-2 polypeptide. The Examiner has also suggested specific claim language that would obviate the rejection.

In response, Applicants amendment renders this part of the rejection moot.

The rejection in the second part is an extension of the new mater rejection referring to the previous addition of the term “specifically.” Applicants’ prior discussion of support for this term, is also applicable to a discussion for why this term is not indefinite. Additionally, responsive to the Examiner’s suggestion that “specific” perhaps might mean binding with greater specificity than other proteins, Applicants direct the Examiner’s attention to page 24, lines 13-14 in which “binding affinity” is introduced as a distinct concept from “binding specificity”. Applicants respectfully submit that the term is not indefinite.

The rejection in the third part is directed to an alleged confusion arising from the word order of “conservatively substituted, added or deleted.” Applicants amendments renders the rejection moot.

Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 29-54 are rejected under 35 U.S.C. § 112, Second Paragraph.

Rejection Under 35 U.S.C. § 103(a) (cited references)

Claims 29-33, 35-43, 45-49 and 51-54 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Motoyama *et al.*, *Nat. Genet.* 18(2): 104-6 in view of Tso *et al.*, USP 5,932,448.

In response, neither Motoyama, nor Tso *et al* disclose antibodies that specifically binding to USP 5,932,448.

Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 29-33, 35-43, 45-49 and 51-54 under 38 U.S.C. § 103(a) over Motoyama *et al.*, ,*Nat. Genet.*

18(2): 104-6 in view of Tso *et al.*, USP 5,932,448.

SUMMARY

Claims 29-30, 36-40, 46-49 and 52-54 remain in this application. Claims 29, 39 and 49 are amended. Claims 1-28 were previously canceled and Claims 31-35, 41-45 and 50-51 are cancelled without prejudice to later prosecution. Applicants further retain the right to pursue withdrawn, non-elected, cancelled, and/or disclosed, but unclaimed subject matter in subsequent prosecution.


If in the opinion of the Examiner, a **telephone conference** would expedite the prosecution of the subject application, the Examiner is **strongly encouraged** to call the undersigned at the number indicated below.

This response/amendment is submitted with a transmittal letter and petition for a 3-month extension of time and fees. In the unlikely event that this document is separated from the transmittal letter or if fees are required, applicants petition the Commissioner to authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
GENENTECH, INC.

Date: October 4, 2006

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